

## **II. REMARKS**

No amendment to the claims is made by the present paper. Remarks and arguments pertaining to the patentability of the claimed invention follow below.

### **A. The Invention**

The present invention relates to a blood access device for hemodialysis that is of a no-needle type. More specifically, in accordance with an embodiment of the present invention, a no-needle blood access device for hemodialysis is provided that includes the limitations recited by independent claim 1. In accordance with another embodiment of the present invention, a no-needle blood access device for hemodialysis is provided that includes the limitations recited by independent claim 13.

With the invention, the artery or vein will be in communication with the dialyzer without leakage of blood, so that hemodialysis can be done without a caregiver. The device of the present invention provides these features with a relatively simple structure, enabling manufacture at low cost, and ease of handling.

### **B. The Rejections**

Claims 1, 3, 7, 8, 10 and 11 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kawamura (U.S. Patent 6,231,541 B1, hereafter the “Kawamura’541 Patent”) in view of Montgomery (U.S. Patent 3,358,961, hereafter the “Montgomery Patent”) as evidenced by Abbey (U.S. Patent 2,828,146, hereafter the “Abbey Patent”).

Claim 13 stands rejected under 35 U.S.C. § 102(b) as allegedly “anticipated” by the Kawamura Patent in view of the Montgomery Patent, and further in view of Sherry (U.S. Patent 6,319,226 B1, hereafter the “Sherry Patent”).

Applicant respectfully traverses the present rejections and requests reconsideration

and allowance of the above-captioned application for the following reasons.

**C. Applicant's Arguments**

**i. The Section 102 Rejection**

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)(emphasis added). In this case, the Examiner has failed to establish a prima facie case of anticipation against claim 13 because the Examiner has not shown that a “single prior art reference” discloses each and every limitation of the claimed invention. As conceded by the Examiner (Office Action, dated October 3, 2008, at 6, lines 12-15), the combination of the Kawamura’541 Patent and the Montgomery Patent does not teach, or suggest, “the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the plane of the skin” as recited by independent claim 13. For this reason alone, the Examiner has failed to establish a prima facie case of anticipation against Applicant’s independent claim 13.

**ii. The Section 103 Rejection**

A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other legitimate reason, for combining the references in the manner claimed. KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 1739-41 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). In this case, the Examiner has failed to establish a prima facie case of obviousness against Applicant’s claimed invention because (i) the combination of the Kawamura’541 Patent, the Montgomery Patent, the Abbey

Patent and the Sherry Patent fails to teach each and every limitation of the claims, and because (ii) the Examiner has failed to demonstrate any legitimate reason for making the claimed combination.

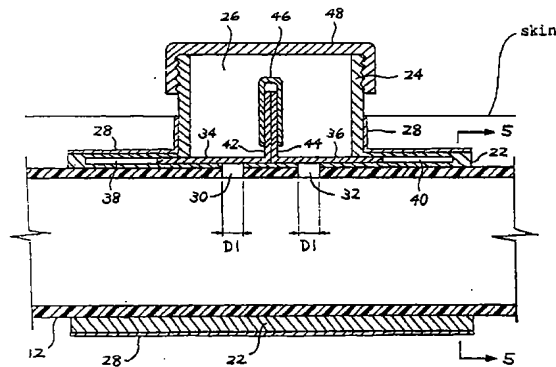
**iii. The Kawamura'541 Patent**

The Kawamura'541 Patent discloses a “no-needle blood access device for hemodialysis and no-needle connecting cannula assembly” that, as shown in Figures 6 and 10, includes (a) an artificial conduit (12) whose opposite ends are anastomosed to a targeted artery or vein; and (b) a metallic body (20), the body including a cylindrical horizontal portion (22) covering the entire circumference of the conduit or an arcuate-shaped horizontal portion (50) covering at least an upper half of the circumference of the conduit, and a cylindrical vertical portion (24) connected to approximately the center of the upper part of the horizontal portion so as to be disposed perpendicular to the horizontal portion and defining a well (26) therein, wherein the horizontal portion is provided at the part located at the bottom of the well with a first pair of apertures (30, 32), and the conduit is provided at the corresponding part with a second pair of apertures (30, 32), whereby the well is in communication with the conduit through the apertures; and (c) a pair of shutters (34, 36) slidably housed within opposed pockets formed in the upper part of the horizontal portion respectively and arranged such that they can be opened and closed (See Abstract of the Kawamura'541 Patent). The Kawamura'541 Patent also discloses that when the shutters (34, 36) are opened, the well (26) is brought into communication with the conduit (12), and when the shutters are closed, the well is brought out of communication with the conduit (See Abstract of the Kawamura'541 Patent).

As shown in Figure 2 of the Kawamura'541 Patent, the shutters (34) and (36) have no holes formed therein. Figure 2 of the Kawamura'541 Patent is reproduced below for the

Examiner's convenience.

FIG. 2



As is evident from Figure 2 and as conceded by the Examiner (Office Action dated October 3, 2008, at 4, lines 14-16), the Kawamura'541 Patent does not teach, or even suggest, "a pair of shutters... each of the shutters including a first through-hole formed therein... each of the first through-holes of the shutters being provided at the vertical portion" as recited by independent claims 1 and 13 of the above-captioned application. In fact, if the shutters (34) and (36) were modified to include holes formed therein, they would not operate as intended to bring the well (26) out of communication with conduit (12) when in the closed state (see Figure 2 and col. 4, lines 43-56). Because such a modification of the shutters disclosed by the Kawamura'541 Patent would obliterate an essential feature of the device disclosed by the Kawamura'541 Patent, it would not be obvious to add through-holes to the shutters (34) and (36) of Kawamura's device. See, e.g., McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010-11 (Fed. Cir. 2001). Furthermore, the addition of holes to the shutters (34) and (36) would serve no purpose when the shutters (34), (36) are in the open state (see Figure 10) because the shutters (34), (36) are then disposed in pockets (38) and (40), respectively.

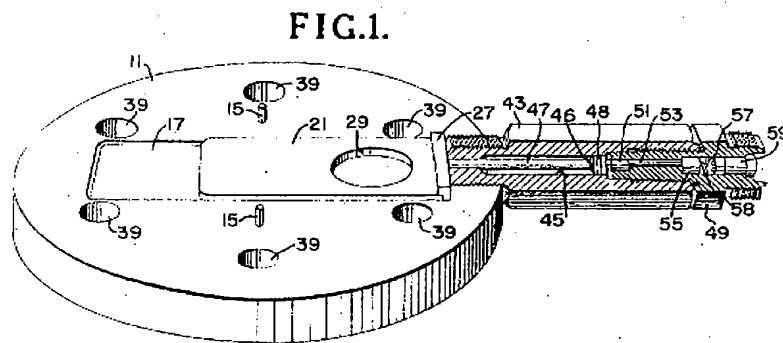
As would be immediately understood by a person of ordinary skill in the art, the device disclosed by the Kawamura'541 Patent requires that shutters (34) and (36) be opened in order to insert the cannulas into the apertures (30) and (32). The presently claimed invention, on the other hand, permits insertion of the cannulas into the apertures (40c) and (42c) without having to open the shutters (40) and (42). Therefore, the patient is able to receive hemodialysis, for example, without the aid of a caregiver.

As also admitted by the Examiner (Office Action, dated October 3, 2008, at 6, lines 12-15), the Kawamura'541 Patent does not teach, or suggest, "the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the plane of the skin" as recited by independent claim 13.

For all of the above reasons, the Kawamura'541 Patent cannot anticipate, or render obvious, the subject matter of independent claims 1 and 13.

**iv. The Montgomery Patent**

The Montgomery Patent discloses an "explosively driven shutter type pressure release apparatus," as shown in Figure 1 reproduced below, wherein an explosive charge (51) is

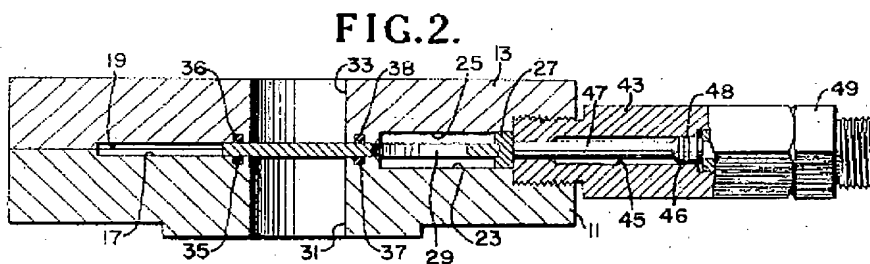


detonated to drive a piston (46) to the other end of cylinder (45) to cause the shutter body (21) to move to the open position with the hole (29) in alignment with the axial holes (31)

and (33) of the valve body (See Montgomery Patent, col. 2, lines 21-36, Figures 1 and 2). A person of ordinary skill in the art would instantly realize that the device disclosed by the Montgomery Patent has some sort of military application and is, therefore, non-analogous art. Furthermore, a person of ordinary skill in the art would not look to a valve that operates based on an explosive charge for structure to apply to a “no-needle blood access device” of the present invention, such as may be used for hemodialysis.

Furthermore, the valve structure disclosed by the Montgomery Patent employs a single shutter body (21), which is substantially different from Applicant's claimed invention, which employs "a pair of shutters." However, this is not the only difference between the subject matter disclosed by the Montgomery Patent and Applicant's claimed invention. The Montgomery Patent does not teach, or suggest, "each of the shutters including a first through-hole formed therein... each of the first through-holes of the shutters being provided **at the vertical portion**" as recited by independent claims 1 and 13. In fact, if the Montgomery device had such a structure, the shutter body (21) would be inoperative.

As evident from Figure 2 of the Montgomery Patent, reproduced below for convenience, the shutter body (21) **does not have** a “horizontal portion” and a “vertical portion” wherein “the first through-holes of the shutters being provided at the vertical portion” as recited by independent claims 1 and 13. However, this is not the only deficiency



in the disclosure of the Montgomery Patent. As admitted by the Examiner (Office Action,

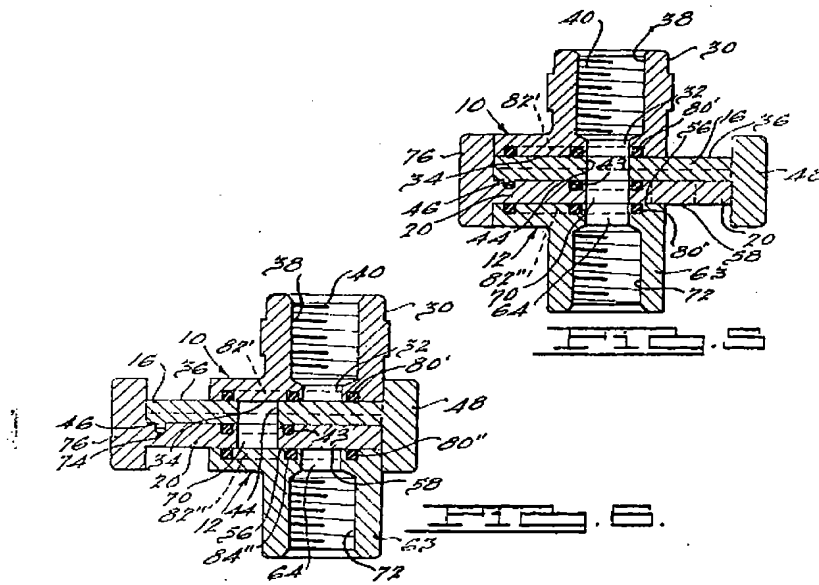
dated October 3, 2008, at 6, lines 12-15), the Montgomery Patent does not teach, or suggest, “the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the plane of the skin” as recited by independent claim 13.

**v. The Abbey Patent**

The Abbey Patent discloses a “coupling with sliding seal plates,” as shown in Figures 1-6, wherein a coupling part (10) comprising a body part (14) and an associated sliding valve plate (16), and another coupling part (12) comprising body part (13) and associated sliding valve plate (20), are assembled together so that the sliding valve plates (16) and (20) form a slidable passageway comprising plate openings (44) and (70), (Abbey Patent, col. 2, lines 32-57, and col. 3, lines 20-23). Finger actuated end portions (48) and (76) are provided so that the sliding valve plates (16) and (20) may be actuated (Abbey Patent, col. 2, lines 58-63, and col. 4, lines 18-28).

A person of ordinary skill in the art would appreciate that the Abbey Patent is non-analogous art because it pertains to a device for industrial use and not to a “no-needle blood access device” as is the subject matter of the invention of the above-captioned application.

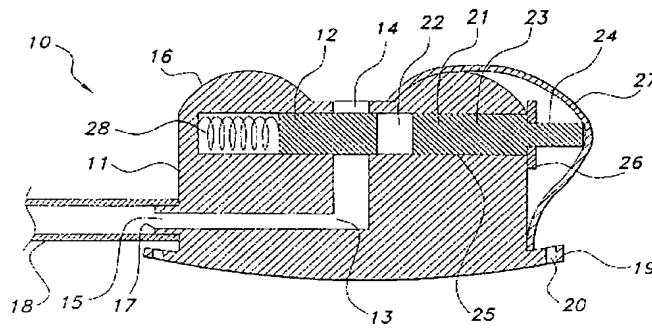
As evident from Figures 5 and 6 of the Abbey Patent, reproduced below for convenience, sliding valve plates (16) and (20) do not include a “horizontal portion” and a “vertical portion” wherein “the first through-holes of the shutters being provided at the vertical portion” as recited by independent claims 1 and 13. In fact, the sliding valve plates disclosed by the Abbey Patent would be inoperative if each were provided with such a “vertical portion.”



#### vi. The Sherry Patent

The Sherry Patent discloses an “implantable vascular access device,” such as shown in Figures 1A, 1B, 2A and 2B, wherein the implantable vascular access device (10) includes a housing (11) having an inlet (14), an outlet (15), an interior conduit (13) defined therein and a valve (12) positioned between the inlet and the outlet, wherein the valve (12) is subcutaneously manipulated between an open position, in which fluid can flow between the inlet and the outlet, and a closed position in which the valve occludes the interior conduit (See Abstract of the Sherry Patent, and Figures 1A and 1B). Figure 1A is reproduced below for the Examiner’s convenience. Sherry’s device may also include a combination of multiple inlets, outlets and/or interior conduits or chambers and may further include an additional cannula valve, and the housing may include two separate interior conduits suitable for the inflow and outflow of a typical hemodialysis procedure (See Abstract of the Sherry Patent).





**FIG 1A**

However, as evident from Figure 1A of the Sherry Patent, the elongate member (21) of the valve (12) does not include a “horizontal portion” and a “vertical portion” wherein “the first through-holes of the shutters [are] provided at the vertical portion” as recited by independent claims 1 and 13. In fact, the elongate member (21) disclosed by the Abbey Patent would be inoperative if it were provided with such a “vertical portion.”

**vii. The Examiner’s “Official Notice”**

The Examiner appears to take “Official Notice” that it is common knowledge that “shutter type slide valves for opening and closing fluid flow passageways were known in the art,” such as shown by the Abbey Patent, so that the shutter type slide valves disclosed by the Abbey Patent, and/or the Montgomery Patent, are somehow “equivalent” to the valves disclosed by the Kawamura’541 Patent (See, e.g., Office Action, dated October 3, 2008, at 5, lines 4-21). Applicant objects to the Examiner’s “Official Notice” for the following reasons.

First, the Patent Office cannot remedy a deficiency in the teaching of one or more references merely by asserting what is “basic knowledge” in the art; rather, the Patent Office must demonstrate all claim limitations based on substantial evidentiary support. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). Second, Applicant previously objected to the Examiner’s “Official Notice” (See Amendment (D), filed , at 15, lines 15-24). Third, the

Abbey Patent does not teach, or suggest, that the valve structure disclosed by the Abbey Patent is “equivalent” to the valve structure disclosed by the Kawamura’541 Patent.

In sum, Applicant contends that the “Official Notice” is a pretext for circumventing the Examiner’s obligation to comply with the Administrative Procedure Act’s requirement that rejections employ “reasoned decision making” based on evidence from a fully developed administrative record. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). In other words, patentability determinations, such as those employed by the Examiner, that are based on what the Examiner believes is “basic knowledge” and “common sense,” and that otherwise lacks substantial evidentiary support, are impermissible. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed.Cir. 2001). Therefore, Applicant respectfully traverses the Examiner’s Section 103 rejection of claims 1 and 13 on the grounds that the “Official Notice” lacks “substantial evidentiary support.” Therefore, the Examiner must now adduce substantial evidentiary support (e.g., produce a legitimate prior art reference) with respect to the subject matter of the “Official Notice” or withdraw the obviousness rejections.

Applicant also objects to the Examiner’s mischaracterization of the Section 103 rejections. The Examiner explicitly concedes that neither the Kawamura’541 Patent nor the Montgomery Patent provides any legitimate reason to justify their combination (See Office Action, dated October 3, 2008, at 5, lines 4-10). Whether motivation (i.e., a legitimate reason) to combine prior art has been established is a question of fact. McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001). Therefore, assuming *arguendo* that the Abbey Patent did provide a legitimate reason to combine the Kawamura’541 Patent and the Montgomery Patent (which is an erroneous assumption), then the Examiner’s Section 103 rejection of claim 1 would be properly characterized as the combination of the Kawamura’541 Patent, the Montgomery Patent, and the Abbey Patent, and the rejection of

claim 13 would be properly characterized as the combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent.

**viii. Summary of the Disclosures**

The combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent fails to teach, or even suggest, "each of the shutters including a first through-hole formed therein... **each of the first through-holes of the shutters being provided at the vertical portion**" as recited by independent claims 1 and 13.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against independent claims 1 and 13 of the above-captioned application.

**ix. No Legitimate Reason to Combine the Disclosures**

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). As admitted by the Examiner, neither the Kawamura'541 Patent nor the Montgomery Patent provides any legitimate reason to justify their combination (See Office Action, dated October 3, 2008, at 5, lines 4-10). Instead, the Examiner appears to give "Official Notice" that it is known in the art that the valve structure disclosed by the Montgomery Patent is "equivalent" to the valve structure disclosed by the Kawamura'541 Patent based on the disclosure of the Abbey Patent. Applicant disagrees because the Abbey Patent does not teach, or suggest, the valve structure disclosed by the Kawamura'541 Patent or the valve structure disclosed by the Montgomery

Patent. Therefore, the Abbey Patent cannot teach, or suggest, that these valve structures are “equivalent” as the Examiner contends.

Furthermore, the Montgomery Patent is non-analogous art used for some heavy-duty industrial and/or military use. The Montgomery Patent further discloses the use of an explosive charge to move the shutter valve. A person of ordinary skill in the art would not look to the explosive valve assembly disclosed by the Montgomery Patent for structure to employ in a medical device such as Applicant’s “no-needle blood access device.” The structure disclosed by the Abbey Patent is likewise intended for industrial use and is, therefore, also non-analogous art.

A “no-needle blood access device,” in accordance with the presently claimed invention, includes a pair of shutters wherein each shutter can be opened or closed from the top side. The devices disclosed by the Montgomery Patent and the Abbey Patent, on the other hand, involve opening and closing of a shutter valve that can only be conducted from the side position. The device disclosed by the Kawamura’541 Patent requires insertion of cannulas into apertures (30) and (32) by first opening the shutters (34) and (36). The present invention permits insertion of cannulas into the apertures without having to first open the shutters, which makes it possible for a patient to receive hemodialysis without the assistance of a caregiver. With respect to the Sherry Patent, this device has a complex mechanism and a non-realistic structure when compared to the presently claimed invention. A person of ordinary skill in the art would realize that it would be difficult for a patient to receive, for example, hemodialysis outside of a medical facility using the device disclosed by the Abbey Patent.

For all of the above reasons, the Examiner has failed to establish any legitimate reason for combining the disclosures of the Kawamura’541 Patent, the Montgomery Patent,

the Abbey Patent, and the Sherry Patent. Therefore, the Examiner has failed to establish a prima facie case of obviousness against independent claims 1 and 13.

**x. No Reasonable Expectation of Success Even if the Combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent Were Made**

A proper rejection under Section 103 requires showing that a person of ordinary skill in the art would have had a reasonable expectation of success of achieving Applicant's claimed invention if the combination of prior art asserted was made. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, the Examiner has not demonstrated that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at Applicant's claimed invention even if the combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent was made.

As discussed above, neither the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, nor the Sherry Patent, either alone or in combination, teach or suggest, "each of the shutters including a first through-hole formed therein... **each of the first through-holes of the shutters being provided at the vertical portion**" as recited by independent claims 1 and 13. Specifically, the Kawamura'541 Patent disclosed valves that have no through-holes. The Montgomery Patent, the Abbey Patent, and the Sherry Patent each disclosed valves employing a shutter having a through-hole formed therein. However, the through-hole is not formed in vertical portion of the shutter valve. In fact, as evident from the figures discussed above, if the shutter valves disclosed by the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and/or the Sherry Patent were modified so that the through-hole was formed in a "vertical portion" of the shutter valve, then these shutter valves

would be inoperative because the through-hole would not be alignable with a fluid passage of the valve.

The Federal Circuit has ruled that a modification of a prior art device that would render it inoperative for its intended purpose cannot serve as a basis for establishing a valid case of prima facie obviousness. In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Therefore, the Examiner cannot establish a prima facie case of obviousness based on the disclosures of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent because these four references fail to teach, or suggest, "each of the shutters including a first through-hole formed therein... **each of the first through-holes of the shutters being provided at the vertical portion**" as recited by independent claims 1 and 13, and because if these four devices were modified to include such a feature, it would render them inoperable.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against independent claims 1 and 13 of the above-captioned application.

### **III. CONCLUSION**

The Section 102(b) rejection standing against independent claim 13 is untenable and must be withdrawn because it is not based on the disclosure of a single prior art reference. In addition, the Examiner has failed to establish a prima facie case of obviousness against claims 1, 3, 7, 8, 10, 11, and 13 of the above-captioned application because (i) the combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent fails to teach, or suggest, "each of the shutters including a first through-hole formed therein... **each of the first through-holes of the shutters being provided at the vertical portion**" as recited by independent claims 1 and 13, (ii) the Examiner has failed to establish a legitimate reason to justify the combination, and (iii) because the Examiner has

failed to demonstrate that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at Applicant's claimed invention if the combination of the Kawamura'541 Patent, the Montgomery Patent, the Abbey Patent, and the Sherry Patent was made.

For all of the above reasons, claims 1, 3, 7, 8, 10, 11, and 13 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below signed attorney for the Applicants.

Respectfully submitted,

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